

VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
Meat and Poultry Inspection Service
MONTPELIER, VT
Chuck Ross, Secretary



MIS DIRECTIVE

Adopted from FSIS Directive 5420.1 Rev. 7

5420.1,
Revision 7

9/1/11

FOOD DEFENSE VERIFICATION PROCEDURES AND NATIONAL TERRORISM ADVISORY SYSTEM ALERT RESPONSE FOR THE OFFICE OF FIELD OPERATIONS

I. PURPOSE

A. This directive describes Food Defense Verification Procedures that Inspection Program Personnel (IPP) are to perform and the frequency with which these procedures are to be performed.

B. On January 27, 2011, the Department of Homeland Security (DHS) announced that it would discontinue the color-coded Threat Condition alerts of the Homeland Security Advisory System on April 27, 2011, in favor of a new system, the National Terrorism Advisory System (NTAS).

C. This directive also describes additional actions that are required when DHS issues an NTAS alert.

KEY POINTS

- *A risk-based approach for scheduling Food Defense Verification Procedures;*
- *How NTAS alerts will be communicated;*
- *How to respond to NTAS alerts;*
- *How to effectively address and resolve noted security concerns to ensure that food is protected, thereby protecting public health; and*
- *How to determine whether an establishment has a functional food defense plan*

II. CANCELLATION

VT Directive 5420.1, Revision 6, Homeland Security Threat Condition Response – Food Defense Verification Procedures, dated 08/06/09

III. REASON FOR REISSUANCE

A. FSIS is reissuing this directive to reflect DHS' NTAS, which replaced the

IV. REFERENCES

9 CFR part 300 to end
FSIS Directive 5500.2, Significant Incident Response

V. BACKGROUND

A. Food defense is the protection of food products from intentional adulteration with chemical, biological, physical, or radiological agents. Food defense is an integral part of FSIS' mission of ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged.

B. IPP conduct Food Defense Verification Procedures to identify potential vulnerabilities in establishments that could lead to or allow deliberate contamination. The frequency with which these tasks are to be performed is based on the following three factors that affect the risk of intentional contamination:

1. Nature of the food product: In general, the following characteristics are associated with foods most vulnerable to intentional adulteration:
 - a. Large batch size;
 - b. Uniform mixing;
 - c. Short shelf life; and
 - d. Accessibility to the product

NOTE: The high-risk products identified in Attachment 1 have one or more of these characteristics.

2. Product volume: A greater volume of product can lead to greater consequences of intentional adulteration. The volume threshold was set so that high-volume establishments handle approximately 95% of total product processed.
3. Food defense plan: voluntary food defense plans are an important tool that can reduce the risk of intentional adulteration.

C. When the Federal government receives information about a specific or credible terrorist threat to food or agriculture, the frequency with which Food Defense Verification Procedures are performed will increase, and additional actions may be

needed to reduce the threat of intentional adulteration of food products. Given what is required in responding to a credible threat of a terrorist attack, IPP must clearly understand their roles and what will be required of them to respond properly to that threat.

D. Under the new NTAS system, DHS coordinates with other Federal entities to issue formal, detailed alerts when the Federal government receives information about a specific or credible terrorist threat. These alerts include a clear statement that there is an “imminent threat” or “elevated threat.” The alerts also provide a concise summary of the potential threat, information about actions being taken to protect public safety, and recommended steps that individuals, communities, businesses, and governments can take.

E. The NTAS alerts are based on the nature of the threat. In some cases, alerts are sent directly to law enforcement or affected areas of the private sector, while in others, alerts are issued more broadly to the American people through both official and media channels—including a designated DHS webpage (www.dhs.gov/alerts), as well as social media tools, including Facebook and Twitter (@NTASAlerts).

F. Additionally, NTAS has a “sunset provision,” meaning that individual threat alerts are issued with a specified end date. Alerts may be extended if new information becomes available or if the threat evolves significantly.

VI. NOTIFICATION

A. If DHS issues an NTAS alert, the FSIS Office of Data Integration and Food Protection (ODIFP) Assistant Administrator (AA) or designee will determine whether the alert affects food or agriculture and, if so, will inform the FSIS Administrator and FSIS Management Council. The ODIFP AA or designee will determine the appropriate distribution of the NTAS alert information and will coordinate with the FSIS Office of Public Affairs and Consumer Education (OPACE) to notify employees, stakeholders, and the public, as appropriate. In the case of a significant incident, the FSIS Emergency Management Committee may be alerted or activated and other response actions taken pursuant to Directive 5500.2.

B. Vermont Emergency Management also operates a fusion center with the DHS, FBI, and other state and federal entities. If VEM becomes aware of a specific or credible threat through the fusion center, it will notify the VT Agency of Agriculture.

NOTE: Inspectors-in-Charge (IICs) are to ensure that any notifications distributed to field employees pursuant to this directive are available to food inspectors. IICs will also inform establishment management of the NTAS alert.

C. When an NTAS alert ends, ODIFP will notify the FSIS Administrator and the FSIS Management Council. ODIFP will coordinate with OPACE to notify employees, stakeholders, and the public, as appropriate. The IICs will advise the establishment management of the change in NTAS alert status.

VII. FOOD DEFENSE ACTIVITIES

A. All IPP in meat and poultry establishments and processed egg products plants are to perform Food Defense Verification Procedures (08S) listed in Section X, Inspection System Procedure (ISP) codes 08S14-08S17.

B. IPP in meat and poultry establishments are to:

1. Perform the 08S procedures at the frequency prescribed in Section VIII, Table 1.
2. Record in the Performance-Based Inspection System (PBIS) the 08S procedures as UNSCHEDULED procedures within the established tour of duty. If IPP need to replace procedures in order to perform the 08S procedures, first they are to replace scheduled 04 procedures and, if necessary, they are to replace HACCP 01 procedures to ensure that the number of prescribed 08S procedures are performed. IPP are to refer to the chart in Attachment 1 to prioritize which HACCP procedures to replace, if necessary. If there are multiple scheduled HACCP procedures, select the ones for the lowest risk type of product as listed in the chart in Attachment 1.

D. All IPP are to enter a result code “3” in PBIS for any scheduled procedure that they replace with a 08S procedure.

E. IICs assigned to multi-shift establishments are to use the established information-sharing practices to ensure that the 08S procedures are performed on the prescribed risk-based frequencies. The frequency of alternating the 08S procedure across shifts should be on either a weekly or a bi-weekly basis. The Inspection Chief or Head of Service will provide any necessary oversight.

F. In the case of an NTAS alert identifying an imminent threat to food or agriculture, the IIC will receive specific instructions from the Agency on other measures that he or she is to take based on information received about the specific threat to a product or process. Such measures may include sampling of specific products, if warranted, to protect public health. The Agency will make sure it has an on-site presence in establishments producing the products named in the NTAS alert during any type of operational activity.

VIII. FREQUENCY AND NUMBER OF 08S PROCEDURES IN MEAT AND POULTRY ESTABLISHMENTS

Table 1
Frequency and Number of 08S Procedures in Meat and Poultry Establishments

Vulnerability	No Active NTAS Alerts, or Active Alert with No Specific Threat to Food or Agriculture	NTAS Alert with Elevated¹ Threat to Food or Agriculture	NTAS Alert with Imminent¹ Threat to Food or Agriculture
High-Risk Products/ High Volume	3 per week ^{2,3} 1 per week ⁴	4 per day	4 per day
High-Risk Products/ Low Volume	1 per week ² 1 every other week ⁴	2 per day	4 per day
Low-Risk Products/ Any Volume	1 per week ² 1 every other week ⁴	2 per day	4 per day

¹ The NTAS alerts state whether there is an “imminent threat” or “elevated threat.”

² This frequency is for establishments that do not have a functional food defense plan.

³ IPP are to perform one 08S procedure per week in establishments that operate 2 days or fewer per week.

⁴ This frequency is for establishments that have a functional food defense plan.

A. Risk Definitions for Table 1

1. High-risk products include all products under product categories 03B, 03C, 03E, 03F, 03G, 03H, and 03I.
2. Low-risk products include all other product categories not listed in 1 above.

B. Volume Definitions for Table 1

1. High-volume establishments are those producing more than 3 million pounds per year (total of meat and poultry products produced).
2. Low-volume establishments are those producing less than 3 million pounds per year (total of meat and poultry products produced).

C. Functional Food Defense Plan Definition for Table 1

For purpose of determining the frequency and number of 08S procedures, an establishment is considered to have a functional food defense plan if it is listed as such in the plant profile, or if the management has stated to the IPP that the establishment has a functional food defense plan (see Section X).

IX. FREQUENCY AND NUMBER OF 08S PROCEDURES IN PROCESSED EGG PRODUCT PLANTS

Table 2
Frequency and Number of 08S Procedures in Processed Egg Products Plants

Vulnerability	No Active NTAS Alerts, or Active Alert with No Specific Threat to Food or Agriculture	NTAS Alert with Elevated¹ Threat to Food or Agriculture	NTAS Alert with Imminent¹ Threat to Food or Agriculture
Processed Egg Products/ High Volume	3 per week ^{2,3} 1 per week ⁴	4 per day	4 per day
Processed Egg Products/ Low Volume	1 per week ² 1 every other week ⁴	2 per day	4 per day

¹ The NTAS alerts state whether there is an “imminent threat” or “elevated threat.”

² This frequency is for establishments that do not have a functional food defense plan.

³ IPP are to perform one 08S procedure per week in establishments that operate 2 days or fewer per week.

⁴ This frequency is for establishments that have a functional food defense plan.

A. Volume Definitions for Table 2

1. High-volume establishments are those producing more than 2 million pounds per year (total of all processed egg products produced).
2. Low-volume establishments are those producing less than 2 million pounds per year (total of processed egg products produced).

B. Functional Food Defense Plan Definition for Table 2

For purpose of determining the frequency and number of 08S procedures, an establishment is considered to have a functional food defense plan if it is listed as such in the plant profile, or if the management has stated to the IPP that the establishment has a functional food defense plan (see Section X).

X. FOOD DEFENSE PLAN

A. FSIS and VTMIS has urged establishments to develop functional food defense plans to set out control measures to help prevent intentional adulteration of product. Although not required, these plans are considered to be important preparatory measures. A functional food defense plan has the following characteristics: it is written, the measures described in the plan are implemented, the measures are periodically tested, and the plan is reviewed at least annually and revised if needed. The Agency has developed guidelines on the food defense plans, which are available on the FSIS web site at:

http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp.

B. An establishment is not obligated to share a copy of its written plan with IPP. If an establishment does share the plan, IPP are only to use the plan to help them identify how the establishment is addressing food defense. If the establishment is not implementing elements of its plan, IPP cannot take action on that fact because there is no regulatory requirement for such plans. IPP are not to show or share the plan with any outside source because it may contain sensitive information.

C. Establishments may choose to develop a functional food defense plan at any time or decide to share plans they already developed. In such cases, IPP are to discuss such plans at the weekly meeting (See FSIS Directive 5000.1). IPP are to document in the weekly meeting memorandum that a plan was shared or discussed with them, as described in FSIS Directive 5000.1.

XI. FOOD DEFENSE VERIFICATION PROCEDURES

A. The purpose of the following Food Defense Verification Procedures is to identify potential weaknesses in the food defense of an establishment that could make it vulnerable to deliberate contamination. A potential weakness can be any part of the food production system where a measure should be implemented to protect it from deliberate contamination, but such a measure is found to be missing or not in place. Examples of potential weaknesses include:

1. Unrestricted access to water systems;
2. Unrestricted access to a processing room; or
3. Uncontrolled access to a restricted ingredient area.

B. Water systems – 08S14:

1. At minimum, IPP are to:
 - a. Observe the security of the establishment's water systems, especially well water, ice storage facilities, and water reuse systems;
 - b. Pay special attention to water used to prepare injection solutions and water and ice used in emulsification (for the production of deli meats and hot dogs); and
 - c. To a lesser extent, check water used to prepare surfactant, antimicrobial agent sprays, and chill tank recharge
2. IPP should also determine whether the establishment:

- a. Controls access to private wells;
- b. Appropriately secures potable water lines or storage tanks; and
- c. Appropriately secures ice storage facilities

C. Processing/Manufacturing – 08S15:

1. At minimum, IPP are to:

- a. Observe production processes (e.g., raw product handling, processing, and packaging of final product) in which exposed products are being handled for indications of attempts to introduce contaminants into the product;
- b. Observe, in particular, operations where the establishment mixes bulk products (e.g., process monitoring by establishment personnel at balance tanks, grinding/emulsification of meat and poultry products, solution injection in preparation areas); and
- c. Observe whether the establishment has procedures in place to prevent deliberate contamination (e.g., camera surveillance, closed systems, or restricted access of personnel to sensitive production areas)

2. IPP should also:

- a. Check a production process (e.g., ground beef production area) for evidence of possible intentional product contamination;
- b. Check to determine whether the establishment has implemented a system to restrict access to sensitive processing areas where bulk products are mixed or processed (e.g., camera surveillance, color-coded uniforms, identification badges, or sign-out sheets);
- c. Check calibration records of equipment (if any) used to dispense restricted ingredients

D. Storage Areas – 08S16

1. At a minimum, IPP are to:

- a. Observe products in cold and dry storage areas for evidence of tampering;
- b. Pay special attention to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification;

- c. Check dry ingredients, including spices, breadings materials, and those used in injection solution preparations, for indication of tampering;
 - d. Observe the use and storage of any hazardous materials in the establishment;
 - e. Verify whether entry into such storage areas is controlled, and that usage logs are maintained and current;
 - f. Pay special attention to cleaning materials, particularly those used in clean-in-place systems;
 - g. Pay special attention to areas where bulk products are mixed (e.g., storage silos); and
 - h. Verify the control of laboratory reagents and cultures
2. IPP should also verify that the establishment has implemented:
- a. Access control procedures to dry ingredient areas;
 - b. Access control procedures to raw product storage areas;
 - c. Access control procedures to finished product storage areas;
 - d. Control procedures for access and use of hazardous chemicals; and
 - e. Observation procedures of all products in storage for evidence of tampering

E. Shipping and Receiving – 08S17

1. At a minimum, IPP are to:
- a. Observe loading dock areas and vehicular traffic in and out of the establishment;
 - b. Report immediately all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management;
 - c. Verify that the establishment secures, when possible, dry and cold products stored in on-site trailers and parks the trailers in a restricted access area of the facility;
 - d. Verify that the facility security staff routinely check the trailers' physical integrity (e.g., locks, seals, and general condition); and

- e Pay special attention to storage silos, combo bins of meat trim, and dry ingredients

2. IPP should also:

- a. Check to determine whether the establishment has procedures in place to restrict or control access to the loading dock area and verify that the establishment has implemented these access control procedures;
- b. Observe incoming raw materials to verify that the establishment checks deliveries against shipping documents. Pay special attention to tanker trucks, dry ingredients, combo bins of fresh meat trim or poultry parts, and boxes of frozen trim that the establishment will ship for further processing

XII. FOOD DEFENSE VERIFICATION PROCEDURE IN IDENTIFICATION WAREHOUSES

A. IPP are to conduct one Food Defense Verification Procedure in identification warehouses when performing voluntary inspection services as set out in FSIS Directive 12600.1, Voluntary Reimbursable Inspection Services. Considering that the warehouses are low-risk, non-food-production facilities, no more than one Food Defense Verification Procedure is to be performed at a facility during the course of one month, unless otherwise instructed pursuant to paragraph C, below. IPP are not to include the time to perform the Food Defense Procedures in the reimbursable service charges. IPP are to conduct this Food Defense Procedure during their established tour of duty, unless advance approval for the use of non-reimbursable overtime is provided by the DO.

B. IPP are to randomly conduct one of the following procedures:

- a. Water Systems– 08S14;
- b. Storage Area – 08S16;
- c. Shipping and Receiving – 08S17

C. IPP will be notified through supervisory channels if it becomes necessary to increase the number of Food Defense Verification Procedures or conduct other food defense activities because of an NTAS alert indicating an elevated or imminent threat to food or agriculture.

XIII. DOCUMENTING FOOD DEFENSE VERIFICATION ACTIVITIES

A. IPP are to record the performance of the 08S procedures and document findings in the following manner:

1. When IPP perform a 08S procedure and do not find a food defense vulnerability or concern, they are to record the procedure as performed by recording trend indicator “A.”
2. When IPP perform a 08S procedure and find that there is a food defense vulnerability or concern, but there is no evidence of product adulteration, they are to record the procedure as performed by recording trend indicator “S” and are to:
 - a. Notify the establishment management and discuss the findings (e.g., at the next weekly meeting); and
 - b. Complete FSIS Form 5420-1 (Food Defense Memorandum of Interview) in PBIS and record establishment response after discussing the findings
3. When IPP perform a 08S procedure and find that there is a food defense vulnerability or concern, and there is evidence of product adulteration, they are to record the procedure as performed by recording trend indicator “T” and are to:
 - a. Immediately notify the facility management and discuss the findings and take action as per established policy;
 - b. Immediately report any potentially significant incident through supervisory channels in accordance with Directive 5500.2, Revision 4;
 - c. Complete a Noncompliance Record (NR) for the product adulteration and cite the appropriate ISP code and regulations; and
 - d. Complete FSIS 5420-1 in PBIS
4. When trend indicator “S” or “T” is entered in PBIS, the Vulnerability Report section of the screen is activated. Once this screen is activated:
 - a. IPP are to click on the down arrow next to the Occurrence field and select:
 - i. “(First)”, if this is the first occurrence of this vulnerability;
 - ii. “(Second)”, if this is the second occurrence, or
 - iii. “(Third)”, indicating the third occurrence

NOTE: For a finding to be reported as the second or third occurrence of a vulnerability, it is to be for the same vulnerability under the performed 08S procedure as occurred previously.

- b. Verify that the name of the IPP that appears in the Inspector field is the name of the person who performed the procedure. To change the name:

- i. Click the magnifying glass icon next to the name field to open the Change Name Window;
- ii. Click the Browse button;
- iii. Select the appropriate name from the list;
- iv. Click the Select button;
- v. Select applicable vulnerabilities by clicking the box adjacent to the vulnerability statement;
- vi. Enter management's response, if any, to each vulnerability selected in the Est. Mgmt Response section; and
- vii. Review the information entered, make changes if necessary, and then click Save.

B. IPP are to provide establishment management with a copy of the completed FSIS Form 5420-1, Food Defense Memorandum of Interview. To print FSIS Form 5420-1 in PBIS, IPP are to:

1. Print from the Procedure Results screen by highlighting the appropriate 08S procedure and click the Print button; or
2. Print from the PBIS pull-down menu:
 - a. Select Reports/Results/Vulnerability Report;
 - b. Select the date range;
 - c. Select the establishment/shift, then click OK, and a new window will appear;
 - d. Select one or more vulnerability reports from the list and click OK; and
 - e. Select the report destination—Enter S for screen, P for printer, or R for an RTF file, then click OK

XIV. MULTIPLE OCCURRENCES OF THE SAME FOOD DEFENSE VULNERABILITY

A. If IPP encounter a second occurrence of a potential food defense vulnerability or concern, they are to meet with the establishment management and complete a second FSIS Form 5420-1 regarding this vulnerability. IPP are to note on the FSIS Form 5420-1 that this is the second occurrence of this vulnerability.

NOTE: As stated above, the occurrence is to be for the same vulnerability under the performed 08S procedure.

B. If IPP encounter the potential food defense vulnerability or concern for a third time, they are to meet once again with the establishment management, complete a third FSIS Form 5420-1, and note on the form that it is the third occurrence of this vulnerability.

C. If the establishment expresses no intention to address the vulnerability or concern, IPP are to notify the Office of this situation. IPP are not to further review or document the specific potential vulnerability identified in the three issuances of FSIS Form 5420-1 until further instructions. If the procedure is randomly selected, IPP are to direct Food Defense Verification Procedures to establishment activities other than the one identified in the third FSIS Form 5420-1.

D. IPP are to provide a copy of the third FSIS Form 5420-1, the discussion notes, and a copy of the weekly meeting memorandum documenting that the establishment developed a functional food defense plan (if applicable) to the VTMS Office.

E. If requested by the Agency, an assessment will be prepared within 30 days. The assessment will include:

1. A review of the results of the food defense plan survey to determine whether the establishment has a functional food defense plan in place;
2. An assessment of the level of concern that the repeat findings represent; and
3. A determination as to whether the establishment has been afforded sufficient time to mitigate the vulnerability

F. The results and recommendations may be:

1. That, because of the nature of the vulnerability, no specific action by the Agency is needed, and IPP are to no longer consider the situation a vulnerability; or
2. That the establishment will be provided with specific guidance on how it can address the vulnerability

G. If guidance was provided on how the establishment can address the vulnerability, IPP are to meet with the establishment management at the next weekly meeting to inquire about the establishment's next steps, if any. IPP are to document what was discussed at this meeting on the third FSIS Form 5420-1.

Attachment 1

NOTE: Replace scheduled HACCP procedures based on product type beginning at the top and moving downward.

FINISHED PRODUCT TYPE	ISP Codes
Thermally processed, commercially sterile	03D
RTE meat, fully-cooked, without subsequent exposure to the environment	03G
RTE poultry, fully-cooked, without subsequent exposure to the environment	03G
RTE fully-cooked meat	03G
RTE dried meat	03E, 03F
RTE dried poultry	03E, 03F
RTE salt-cured meat	03E, 03I
RTE salt-cured poultry	03E, 03I
RTE fully-cooked poultry	03G
RTE fermented meat (without cooking)	03E
RTE fermented poultry (without cooking)	03E
Raw intact pork	03C, 03J
Raw intact beef	03C, 03J
Raw intact meat – other	03C, 03J
Raw ground, comminuted, or otherwise non-intact pork	03B, 03C
Raw ground, comminuted, or otherwise non-intact meat – other	03B, 03C
Raw otherwise processed meat	03E, 03H, 03I
Raw otherwise processed poultry	03E, 03H, 03I
Raw intact chicken	03C
Raw intact turkey	03C
Raw intact poultry – other	03C
Raw ground, comminuted, or otherwise non-intact beef	03B, 03C
Raw ground, comminuted, or otherwise non-intact poultry -- other	03B, 03C
Raw ground, comminuted, or otherwise non-intact turkey	03B, 03C
Raw ground, comminuted, or otherwise non-intact chicken	03B, 03C